Australian Government
Department of Health and Ageing
Office of the Gene Technology Regulator

22 July 2013

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 121

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for a limited and controlled release of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with requirements of the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this field trial poses negligible risks to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Application number	DIR 121
Applicant	Commonwealth Scientific and Industrial Research Organisation
Project title	Limited and controlled release of safflower genetically modified for increased levels of oleic acid
Parent organism	Safflower (*Carthamus tinctorius* L.)
Introduced genes and modified traits	• Partial gene sequences from safflower *FATB* gene - altered fatty acid composition • Partial gene sequences from safflower *FAD2* gene - altered fatty acid composition • Partial gene sequences from another safflower fatty acid biosynthesis gene[1] - altered fatty acid composition • Truncated *hph* gene from the bacterium *Escherichia coli* - antibiotic resistance selectable marker • *gfp* gene from the jellyfish *Aequorea victoria* - visual marker
Proposed locations	One site located in the ACT and one site in each of the local government areas of Narrabri and Wagga Wagga in NSW
Proposed release size	Up to 1 hectare per site per growing season, with 1 site in the first season and up to 3 sites in the second and third seasons
Proposed release dates	September 2013 – March 2016

[1] The identity of this gene has been declared Confidential Commercial Information. The confidential information was made available to the prescribed experts and agencies that were consulted on the RARMP for this application.

Primary purpose	To evaluate the agronomic performance of up to 190 lines of GM safflower under field conditions

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release are negligible.

The risk assessment process considered how the genetic modification and activities conducted with the GMOs might lead to harm to people or the environment. Risks were characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application (including proposed limits and controls), relevant previous approvals, current scientific/technical knowledge, and advice provided in submissions received from experts, agencies, authorities and the public during consultation on the RARMP. Both the short and long term were considered.

Credible pathways to potential harm that were considered included: unintended exposure to the GM plant material; unintended effects of the genetic modification; increased spread and persistence of the GM safflowers relative to unmodified plants; and transfer of the introduced genetic material to non-GM safflowers or other sexually compatible plants. Potential harms associated with these pathways included toxicity to people and other animals, allergic reactions in people and environmental harms associated with weediness. No new risks to people or the environment were identified from the advice received on the consultation RARMP.

The principal reasons for the conclusion of negligible risks are that the proposed limits and controls effectively contain the GMOs and their genetic material and minimise exposure; the introduced genetic modifications are unlikely to cause harm to people or the environment; and genes similar to most of the introduced genes are common in the environment.

Risk management plan

The risk management plan concludes that risks posed by the proposed dealings can be managed so as to protect people and the environment by imposing conditions on the release. Risk management is used to control or mitigate risk. The risk management plan evaluates and treats identified risks, evaluates controls and limits proposed by the applicant, and considers general risk management measures. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, as this is a limited and controlled release, the licence includes limits on the size, locations and duration of the release, as well as controls including containment provisions at the trial site; prohibiting the use of GM plant materials in human food or animal feed; destroying GM plant materials not required for further studies; transporting GM plant materials in accordance with the Regulator's guidelines; and conducting post-harvest monitoring at the trial site to ensure all GMOs are destroyed.